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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/073,863 | 02/14/2002 | Gholam A. Peyman | 42561 | 6337 |

7590 08/19/2003
Roylance, Abrams, Berdo & Goodman, L.L.P.
Suite 600
1300 19th Street, N.W.
Washington, DC 20036

EXAMINER

SHEIKH, HUMERA N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

3

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/073,863 | | PEYMAN, GHOLAM A. | |
| | Examiner | | Art Unit | |
| | Humera N. Sheikh | | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statement filed 08/28/03 is acknowledged.

Claims 1-34 are pending. Claims 1-34 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8, 9, 10, 12, 18 and 19 rejected under 35 U.S.C. 102(b) as being anticipated by Zeimer (US Pat. No. 5,935,942).

Zeimer discloses methods and materials for chemically treating a target site by utilizing fluorescent dyes and tissue-reactive substances that are encapsulated within heat-sensitive liposomes, wherein the liposomes release their contents of fluorescent dyes at a temperature of approximately 41°C without causing thermal damage to tissue (see reference column 3, line 10 through col. 7, line 64); and abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 4-7, 11, 13-17 and 20-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Zeimer (US Pat. No. 5,935,942) in view of Khoobehi *et al.* (US Pat. No. 5,976,502).

Zeimer, as discussed above, teaches methods and materials for chemically treating a target site by utilizing fluorescent dyes and tissue-reactive substances that are encapsulated within heat-sensitive liposomes, wherein the liposomes release their contents of fluorescent dyes at a temperature of approximately 41°C without causing thermal damage to tissue (see reference column 3, line 10 through col. 7, line 64); and abstract.

According to Zeimer, the method involves co-administering intravenously a fluorescent dye encapsulated within heat-sensitive liposomes and a tissue-reactive agent which is effective to cause chemical tissue damage following its activation; non-invasively heating tissue at a pre-determined anatomical locus within the eye so that the heat-sensitive liposomes leak and release their contents into the blood vessel or sinus at the predetermined locus; exciting the fluorescent dye; visually observing a pattern of fluorescent vasculature which develops at the pre-determined locus; and activating the tissue-reactive agent disposed within the blood vessel or sinus so that the blood vessel or sinus is chemically damaged to an extent sufficient to occlude the vessel or sinus (col. 3, lines 10-24).

Zeimer teaches that the blood vessel or sinus is selectively and non-invasively heated to a temperature of approximately 41°C by irradiating with a laser beam having a wavelength absorbed by blood (col. 7, lines 53-57). This temperature meets the instantly claimed temperature at least 41°C.

The heat-sensitive liposomes include physiologically compatible constituents, such as dipalmitoylphosphatidylcholine and dipalmitoylphosphatidyl-glycerol phospholipids, that permit preparation of liposomes using art-recognized techniques that release their contents at temperatures above those of the mammalian body temperature, i.e., above 37°C. Upon exposure to temperatures at least about 40°C, above mammalian temperature, release occurs by leakage or seepage of the liposomes contents or by lysis of the liposomes (col. 7, lines 10-20).

Additionally, the laser-targeted occlusion method also comprises co-administration of an anti-inflammatory agent or an antibiotic encapsulated within the heat-sensitive liposomes. Antibiotics include anti-bacterial, anti-fungal, anti-neoplastic and anti-parasitic antibiotics. Anti-neoplastic antibiotics include aclacinomycins, bleomycins, chromomycins, mitomycins and the olivomycins (col. 12, lines 51-59).

Zeimer is deficient only in the sense that he does not explicitly teach a first and second fluorescent dye encapsulated into various temperatures.

Khoobehi et al. teach a method of observing blood flow through the eye by injecting a carrier, such as liposomes and blood cells containing the dye, into the blood stream whereby the carrier can contain a single dye or a mixture of different dyes. The mixture can be of a first carrier containing a dye capable of fluorescing when exposed to a laser beam in the visible range and a second carrier containing a dye capable of fluorescing when exposed to a red or infrared laser beam. In addition, the cells can be stained with two different lipophilic dyes where the first dye fluoresces when exposed to a red or infrared laser beam and a second dye fluoresces when exposed to a laser beam in the blue-green spectral range (see reference column 3, line 25 through col. 5, line 5).

Therefore, it would have been obvious to one of ordinary skill in the art to use either a single fluorescent dye or a mixture of different fluorescent dyes as taught by Khoobehi within the methods taught by Zeimer, because Khoobehi explicitly teaches liposomes containing a mixture of dyes which serve to enable the dyes to fluoresce

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when exposed to various types of lasers (i.e., visible range or infrared-spectral range) and similarly Zeimer teaches a method of chemically treating a target site by utilizing fluorescent dyes in order to visualize patterns of fluorescence. The expected result would be a highly effective method of targeting specific tissue sites and observing carriers, particularly liposomes, as similarly desired by the applicant.

Regarding the instantly claimed temperatures at which the fluorescent dyes are released, it is the examiner's position that a skilled artisan, through routine or manipulative experimentation, based on the intended purpose, could determine suitable temperature ranges. Applicants have not shown any surprising or unexpected results that accrue from the use of the instant temperatures. The prior art clearly shows the teaching of targeting tissue sites through the encapsulation of fluorescent dyes and tissue-reactive substances by heat-sensitive lipid vesicles. Hence the instant invention is rendered unpatentable over the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

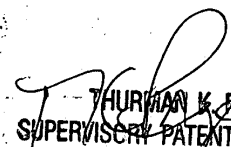
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

August 13, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600